

EXHIBIT F

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., PELVIC) MASTER FILE NO.
 REPAIR SYSTEM PRODUCTS) 2:12-MD-02327
5 LIABILITY LITIGATION) MDL NO. 2327
)
6 THIS DOCUMENT RELATES TO THE) JOSEPH R. GOODWIN
 FOLLOWING CASES IN THE WAVE 1) U.S. DISTRICT JUDGE
7 OF MDL 200:)
 PATTI ANN PHELPS, et al.,) CASE NO.
8) 2:12-cv-01171
 Plaintiff,)
9)
 V.)
10)
 ETHICON, INC., ET AL.,)
11 Defendants.)

12 DEPOSITION OF KIMBERLY H. ALLISON, M.D.
13

14 DATE: THURSDAY, MARCH 17, 2016
15 TIME: 4:10 P.M.
16 LOCATION: STANFORD PARK HOTEL
17 100 El Camino Real
18 Menlo Park, California
19
20

21 Reported by:
22 LUCY CARRILLO-GRUBBS, RMR, CRR, RPR, CRP, CSR
 License No. 6766
23
24
25

1 A P P E A R A N C E S

2 FOR PLAINTIFF:

3 P. LEIGH O'DELL, ESQUIRE
BEASLEY ALLEN CROW METHVIN PORTIS
4 & Miles, P.C.
218 Commerce Street
5 Montgomery, AL 36104
Tel: 334.269.2343
6 Fax: 334.954.7555
Email: Leigh.Odell@BeasleyAllen.com

7

8 FOR DEFENDANTS:

S. PETER VOUDOURIS, ESQUIRE
9 TUCKER ELLIS, LLP
950 Main Avenue, Suite 1100
10 Cleveland, OH 44113
Tel: 216.592.5000
11 Fax: 216.592.5009
Email: peter.voudouris@tuckerellis.com

12

TRACI L. SHAFROTH, ESQUIRE
13 TUCKER ELLIS, LLP
One Market Plaza, Steuart Tower
14 Suite 700
San Francisco, CA 94105
15 Tel: 415.617.2400
Fax::415.617.2409
16 Email: traci.shafroth@tuckerellis.com

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1 Q. All right.

2 Do you know if it's a motor?

3 A. No.

4 Q. Do you know if it's a sensory?

5 A. No.

6 Q. You just know it's there?

7 A. Yes.

8 Q. Any comment on its appearance?

9 MS. O'DELL: Apparent?

10 MR. VOUDOURIS: Appearance.

11 THE WITNESS: Okay.

12 MS. O'DELL: Apparent of a nerve, I'd never
13 heard that before. Appearance.

14 THE WITNESS: No, they're not neuromas, if
15 that's what you're asking.

16 BY MR. VOUDOURIS:

17 Q. No traumatic neuromas?

18 A. No.

19 Q. Are there any ganglia there?

20 A. No, not in this image, no. I don't think
21 I noted ganglia in this particular case.

22 No, I did not.

23 Q. Can you circle for me where you see a
24 foreign body giant cell reaction?

25 A. It's not prominent in this image.

1 Q. Okay.

2 A. I wouldn't circle anything.

3 Q. What do you call this area here
4 (indicating)?

5 A. That looks to me like poor tissue
6 preservation effect. It's paler than the rest of
7 the stain on the slide, and that can happen when
8 the tissue for whatever reason wasn't -- this --
9 this spot didn't process well.

10 Q. Could you put a circle around that,
11 please?

12 A. But the rest of it looks fine.

13 (Witness complies.)

14 Q. So you believe that's due to processing?

15 A. Yes.

16 Q. Could you just mark that?

17 A. (Witness complies.)

18 Q. The tree barking, can you point me to
19 anywhere in your reference literature, any article
20 that describes or ascribes any clinical
21 significance to a patient from this tree barking?

22 A. Iakovlev's the one who has described this,
23 and would you like me to review it? He's looked
24 at --

25 Q. No, that's fine. You're referring to

1 Dr. Iakovlev.

2 A. Okay.

3 Q. Anyone else other than Dr. Iakovlev?

4 A. There are not other pathologists who have
5 published on this particular topic, no.

6 Q. Anything else of significance you want to
7 tell the jury about 8B?

8 A. 8B. No.

9 Q. 8C. What, if anything, would you tell the
10 jury significant about your findings on 8C?

11 A. This is very abnormal skeletal muscle.
12 It's very scarred and fibrotic. The skeletal
13 muscle fibers are -- the fibrosis courses through
14 them in a very abnormal way. This isn't just a
15 scar adjacent to skeletal muscle. This is all
16 scarred area that envelopes the skeletal muscle.
17 And the next page I have some more of the higher
18 powered findings.

19 Q. I'm sorry, are you done? I just want to
20 stick with 8C before I move on.

21 A. Okay.

22 Q. 8C reflects to what on the pathology
23 report that we marked as Exhibit 9?

24 A. Specimen No. 2, rule out foreign material.

25 Q. Again, there's no mesh here?

1 A. There's no mesh here, no.

2 Q. Any nerves here?

3 A. I can't tell from this power.

4 Q. Again, we're at 4X?

5 A. Yes.

6 Q. And you said there was abnormal tissue?

7 A. Scarred skeletal muscle.

8 Q. Why don't you draw where the scarred
9 skeletal muscle is?

10 A. That's the whole image.

11 You want me to indicate the skeletal
12 muscle fiber with an arrow or --

13 Q. However you want to do it.

14 A. (Witness complies.)

15 Skeletal muscle fiber. Fiber, I guess
16 example of one. They're all over. I guess I could
17 circle the whole thing.

18 Q. You just want to circle that, is that what
19 you mean?

20 MS. O'DELL: Well, don't let defense counsel
21 suggest to you what you mean, Dr. Allison.

22 MR. VOUDOURIS: I never want to do that,
23 Dr. Allison.

24 MS. O'DELL: You do what you feel is
25 appropriate.

1 BY MR. VOUDOURIS:

2 Q. You circled skeletal muscle fiber, so
3 that's a fiber right there?

4 A. Yes.

5 Q. There you go, that's all I wanted you to
6 do. Maybe circle a few more so we have an idea.

7 A. This is all scar (indicating), and these
8 nucl- -- these dark spots are multinuclei,
9 atrophic, dead, dying skeletal muscle fibers, but
10 they're better seen on the next image and I'm happy
11 to circle them more on this.

12 This is all scar, this whole thing is scar
13 (indicating).

14 Q. The entire thing is scar?

15 A. It's -- it's all scarred skeletal muscle
16 fibers. It's a very low powered picture of that
17 whole thing.

18 Q. Want to just put that up here, then?

19 A. (Witness complies.)

20 Q. Do you know what a tissue would look like
21 in a woman suffering from pelvic laxity who did not
22 have mesh?

23 A. We don't typically see explants from those
24 patients, but I would not imagine that her skeletal
25 muscle would be this disorganized and scarred.

1 Q. And at Stanford, have you seen skeletal
2 muscle from women who have pelvic laxity that do
3 not have mesh?

4 MS. O'DELL: Object to form. That's too close,
5 Counsel, just --

6 THE WITNESS: No, we don't get those kinds of
7 specimens, as far as I'm aware.

8 MR. VOUDOURIS: Okay.

9 Q. So you haven't; is that correct?

10 A. Correct.

11 Q. All right.

12 What's the next slide?

13 A. So this is a 10X view of one of these
14 areas with the scar engulfing the skeletal muscle
15 fibers.

16 Q. Can you go back and like you did before
17 and do a little box to show what 8D looks like on
18 8C?

19 MS. O'DELL: If you can, don't guess.

20 THE WITNESS: I'm not sure that it's...

21 Yeah, I think it's this area here, so
22 let's put a box (witness complies.)

23 MR. VOUDOURIS: Why don't you make that box a
24 little more definable for everybody.

25 MS. O'DELL: Yeah, I was just about to say

1 tissue, which is the precursor to a scar, so it's
2 organizing fiber vascular tissue that then
3 organizes itself into a scar.

4 Q. So a capillary's in the scar?

5 A. Typically not in the middle of the scarred
6 area, but they can be found on the periphery.

7 Q. Okay.

8 A. Scar tends to push things out of the way.
9 But you have to have some blood vessels feeding any
10 tissue, otherwise it would necrose.

11 So in some way -- I mean, the scar is
12 mainly extracellular material, but there are some
13 cells present as well.

14 Q. 8D I think, I apologize, we're going back
15 and forth, anything else that you want to --
16 anything else of significance on 8D?

17 A. No.

18 Q. And this -- there's scar on this
19 photograph?

20 A. Yes.

21 Q. Where's the scar?

22 A. Again, it's the whole area, the scar is
23 engulfing the entire image, and these are little
24 islands of dying skeletal muscle within it. So I
25 can't really -- I would have to circle the whole

1 area.

2 (Witness complies.)

3 Some areas have, you know, more scar and
4 less skeletal muscle, but the scar's going all the
5 way around these muscle fibers.

6 Q. All right.

7 So can you just label scar, please?

8 A. (Witness complies.)

9 Q. All right.

10 Next, microphotograph 8E. What of
11 significance are you going to tell the jury about
12 8E?

13 A. 8E is an S100 stain which highlights
14 nerves, and in this image you can see multiple
15 nerve fibers present within the tissue around the
16 mesh that has fibrosis in it.

17 Q. Where are the nerves?

18 A. I can circle them.

19 Q. I would hope so.

20 A. (Witness complies.)

21 Q. Thank you. Mark those as nerves.

22 A. (Witness complies.)

23 Q. And you agree with Dr. Vogel's testimony,
24 or at least his report, that using an S100 stain,
25 you're not able to tell whether those nerves are

1 sensory, correct?

2 A. Correct.

3 Q. And you would agree with Dr. Vogel's
4 statement in that regard?

5 MS. O'DELL: Object to the form.

6 THE WITNESS: Yes.

7 BY MR. VOUDOURIS:

8 Q. You see anything abnormal with these
9 nerves?

10 A. Only that they're not present in normal
11 tissue, they're present in scarred tissue around
12 mesh fibers.

13 Q. And that's the only place you find nerves?

14 MS. O'DELL: Object to the form.

15 THE WITNESS: That's not a normal place you
16 find nerves.

17 BY MR. VOUDOURIS:

18 Q. How close are some of these nerves to the
19 mesh fiber?

20 A. Very close.

21 Q. What's very close mean?

22 A. Less than a millimeter.

23 Q. All right.

24 Want to just put here less than a
25 millimeter?

1 A. (Witness complies.)

2 Q. Is there any foreign body giant cell
3 reaction going around this nerve that's less than a
4 millimeter from the mesh?

5 A. You can't appreciate that from this image.

6 Q. Can you appreciate any foreign body giant
7 cell reactions around any of these nerves in 8E?

8 A. No, that's not what this stain is for. It
9 highlights the nerve fibers and it's not -- doesn't
10 give you resolution for the rest of the tissue,
11 that would easily let you -- that's why we use H&E
12 for most of our characterization for the histologic
13 findings.

14 But, you know, it's the same area that we
15 see the chronic inflammation and scarring from the
16 other -- it's the same specimen, from the other
17 images.

18 So 8E is probably taken --

19 Q. These are from specimen one or two?

20 A. One. You'll see the blood vessel up here.
21 With each cut, though, you get slightly different
22 findings at each level, so it's not going to match
23 up perfectly with the pattern of the mesh that
24 you're seeing here.

25 But I would imagine it would be around

1 has proven and confirmed and it's
2 widely accepted that this alleged
3 degradation has any clinical sequelae.")

4 MS. O'DELL: If you've answered his question,
5 just tell him you've given your answer.

6 THE WITNESS: I've given my answer.

7 BY MR. VOUDOURIS:

8 Q. The answer is none, correct?

9 MS. O'DELL: Object to the form.

10 THE WITNESS: I've given my answer.

11 BY MR. VOUDOURIS:

12 Q. The answer is none, correct?

13 MS. O'DELL: Object to the form.

14 THE WITNESS: There is literature looking at
15 degradation.

16 MR. VOUDOURIS: Not my question.

17 THE WITNESS: In patients who have had clinical
18 symptoms.

19 MR. VOUDOURIS: Not my question.

20 MS. O'DELL: It was your question. She
21 answered your question. You can ask it again and
22 she's just going to give the same answer, but she
23 answered your question.

24 BY MR. VOUDOURIS:

25 Q. Handing you as what we've marked as

1 Defendants' Exhibit 4.

2 What is that?

3 A. A reference list.

4 Q. So it's in addition to medical records,
5 the medical literature that you've reviewed in
6 coming to your opinions in this case, correct?

7 A. Yes.

8 Q. Can you circle for me or highlight on that
9 exhibit the literature that proves to a reasonable
10 degree of medical certainty that there is clinical
11 sequelae in vivo from in vivo degradation?

12 MS. O'DELL: Object to the form.

13 THE WITNESS: No.

14 MR. VOUDOURIS: Take a quick break.

15 (Recess.)

16 MR. VOUDOURIS: Back on the record.

17 Dr. Allison, I do not have any more
18 questions for you on Ms. Phelps, pending any
19 recross after your questions by plaintiffs'
20 counsel.

21 -o-

22 EXAMINATION

23 BY MS. O'DELL:

24 Q. I have just a few questions, Dr. Allison.
25 You've been asked a series of questions about the

1 medical and scientific literature supporting your
2 opinions in this case. Dr. Allison, is there
3 literature that you reviewed and relied on to
4 support your conclusion that degradation would
5 cause ongoing chronic inflammation?

6 MR. VOUDOURIS: Objection.

7 THE WITNESS: Yes. In my report, I have all of
8 my references there which support the statements
9 that I make, including -- I mean, I can list them
10 off again like I did in the previous case.

11 Costello, 2007; Iakovlev, 2015; Klinge,
12 2013; Klosterhalfen, 2004; Bendavid, 2014;
13 Riccetto, 2008; Feola, F-e-o-l-a, 2015.

14 BY MS. O'DELL:

15 Q. Without listing them all at this moment,
16 are there other references that support your
17 opinions on your reliance list which has been
18 marked as Exhibit 2 -- or Exhibit 4?

19 MR. VOUDOURIS: Objection, foundation and
20 objection, foundation to the prior question too.

21 THE WITNESS: Well, there's -- it's a long
22 list.

23 There's a lot of literature out there, and
24 of course there are others that I haven't listed in
25 specific -- specifically by name.

1 may answer the question.

2 THE WITNESS: My report covers the mechanisms
3 responsible for the symptoms produced by the mesh,
4 and that they're related to the chronic
5 inflammation and degradation of the mesh while in
6 the body.

7 The nerve entrapment around the fibrosis
8 and scar, and the stiffness that that whole process
9 creates, and that the clinical sequelae are related
10 to all of those things together. I'm not isolating
11 one factor.

12 MR. VOUDOURIS: I am isolating one factor in my
13 question.

14 THE WITNESS: Okay, well --

15 BY MR. VOUDOURIS:

16 Q. Are you stating under oath that the
17 references that you said in your report that we've
18 marked as Exhibit 2, are medical literature that
19 proves that there's a clinical sequelae to the
20 degradation of mesh in vivo?

21 MS. O'DELL: Object to the form.

22 THE WITNESS: We are linking all of these
23 findings together, so...

24 BY MR. VOUDOURIS:

25 Q. Who is "we"?

1 medical literature?

2 A. Yes.

3 Q. And do you believe the medical and
4 scientific literature supports your opinions that
5 you've expressed here?

6 A. Yes.

7 Q. And do you base your opinions here today
8 also on your review of not only the medical records
9 in this case, but also the pathology that you
10 reviewed?

11 A. Yes.

12 Q. And Counsel has pulled out this policy
13 from July of 2006 and suggested that you had
14 somehow given testimony without -- that is false,
15 misleading and without foundation.

16 MR. VOUDOURIS: Objection.

17 BY MS. O'DELL:

18 Q. Is that true?

19 A. No. I do not consider any of my testimony
20 to be false or misleading.

21 Q. And have you endeavored to be
22 straightforward and honest in answering Counsel's
23 questions today?

24 A. Yes, I have.

25 Q. And then Counsel suggested earlier

REPORTER'S CERTIFICATE

I hereby certify that the witness in the foregoing deposition, KIMBERLY H. ALLISON, M.D., was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth, in the within-entitled cause; that said deposition was taken at the time and place herein named; that the deposition is a true record of the witness' testimony as reported by me, a duly certified shorthand reporter and a disinterested person, and was thereafter transcribed into typewriting by computer.

I further certify that I am not interested in the outcome of the said action, nor connected with, nor related to any of the parties in said action, nor to their respective counsel.

IN WITNESS WHEREOF, I have hereunto set my hand 3/21/2016.



LUCY CARRILLO-GRUBBS RPR

CSR No. 6766

STATE OF CALIFORNIA